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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/070,707

07/10/2002

Borje Rantala

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7588

26753 7590 03/27/2007  
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EXAMINER

SCHAETZLE, KENNEDY

ART UNIT

PAPER NUMBER

3766

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/27/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/070,707

Applicant(s)

RANTALA ET AL.

Examiner

Kennedy Schaetzle

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3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 19,23-28 and 30-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19,23-28 and 30-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 18, 2006 has been entered.

### ***Claim Rejections - 35 USC § 112***

2. Claims 28 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original disclosure does not discuss ascertaining the location on the patient of additional remaining electrodes. Determining an electrode configuration does not necessarily imply that the location of the electrodes with respect to the body are determined. Determining an electrode configuration may simply refer to the detection of the number of electrodes plugged into the unit, or the type of electrodes employed. The original disclosure, in fact, discusses the determination of impedance as a means to "...ensure a good quality of the signal..." or to monitor respiratory movement and/or stroke volume (see page 2, 2<sup>nd</sup> paragraph). While a determination of the electrode/skin interface impedance can be described as an assessment of the manner in which electrodes are attached to the body, it does not follow that such a determination can pinpoint electrode location on a patient.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 19 and 23-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swenson et al. (Pat. No. 5,623,925) in view of Donehoo et al. (Pat. No. 5,788,644).

Swenson et al. disclose a medical monitoring system and method comprising the use of multiple electrodes in a universal interface to perform a wide variety of user selectable (see col. 2, lines 48-57) diagnostic tests including, but not limited to, EEG, EKG and EMG (see col. 2, lines 38-47) from a single machine without the necessity of having separate, dedicated test equipment for each different procedure (see col. 3, lines 59-67). While Swenson et al. do not bother to discuss electrode number and type specifics, those of ordinary skill in the medical arts would easily recognize the necessity of employing at least four extremity electrodes and up to six additional electrodes in a standardized 12-lead EKG. Donehoo et al., for example, show the use of such a standardized arrangement in Fig. 2 to collect EKG data. In any event, the adjective used to describe an electrode's location has no bearing on the structure of the electrode. Any suitable biomedical electrode can be semantically labeled an extremity electrode or an additional electrode.

Regarding the attachment of electrodes in a manner suitable for obtaining IKG signal data, the examiner considers any placement of an electrode on the body to be in a manner suitable for obtaining IKG signal data. An impedance signal can be derived from any location including those used for EKG, EEG and EMG monitoring.

Regarding the operation of a switch to select IKG signal data, whether or not one desires to obtain such data is clearly a prerogative of the attending physician and ultimately based on the condition and needs of the patient. Those of ordinary skill in the art given the disclosure of Swenson et al. which emphasizes the importance of providing a highly versatile medical monitor, would have understood the prior art invention to apply to a wide variety of selectable diagnostic tests –not to be limited by the specific tests explicitly mentioned (note col. 1, lines 39-56). Since an IKG test is but

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another diagnostic tool to ascertain a patient's condition, to include such a test among the other standardized tests would have been seen as a matter of obvious design by anyone of ordinary skill in the medical diagnostic arts.

Regarding claim 26, as stated in the Office Action mailed June 15, 2006, Official Notice was taken that it was old and well-known by medical professionals to determine the depth of anesthesia from EEG signal data. As this Notice was not effectively traversed, the feature is now considered to be admitted prior art.

Regarding claim 27, Swenson et al. teach that more than one test may use a common set of conduits (col. 7, lines 28-36). To use a common neutral electrode as a reference for both EKG and ECG would have therefore been considered a matter of obvious design, dependent upon the particular tests being performed. By using common conduits, Swenson et al. eliminate the need for additional, potentially cumbersome and inconvenient lead structure.

5. Claims 28 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swenson et al. and Donehoo et al. as applied to claims 19-27 and 29-31 above, and further in view of Simon et al..

Regarding claims 28 and 32, as best as can be understood, the examiner will consider the phrase "...locations on the patient at which additional remaining electrodes are attached..." to relate to the detection of whether or not the electrodes are located on the body or off the body (note the above rejection of these claims under §112, 1<sup>st</sup> paragraph).

Swenson et al. do not discuss ascertaining the locations of electrodes as determined by impedance relations. Simon et al., however, teach that it is highly beneficial to ascertain such data in order to identify faulty leads and enhance the monitoring accuracy of medical equipment (see col. 1, lines 36-47). To therefore enable similar detection of faulty connections associated with the conduits of Swenson et al. would have been considered blatantly obvious in order to improve signal detection capabilities. In any event, the examiner took Official Notice in a prior Office Action that it was old and well-known in the electrode art to monitor the state of electrode configurations by detecting an impedance signal associated therewith. Lacking an

effective traversal, such a feature was considered admitted prior art in the Office Action mailed June 15, 2006.

**Conclusion**

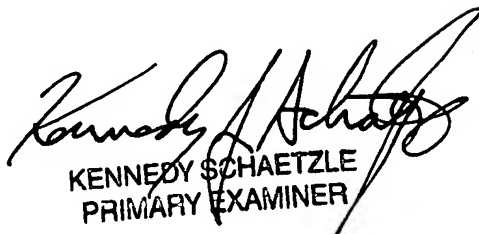
6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on M-F at 571 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KJS  
February 18, 2007

  
KENNEDY SCHAETZLE  
PRIMARY EXAMINER